DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

93096d

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

February 14, 2002

Our Reference: 2954019

Jerry S. Ivers, President
Lafayette Fine Foods, Inc.
Dba Lafayette Caviar & Fine Foods
2504 Third Street
San Francisco, California 94107

WARNING LETTER

Dear Mr. Ivers:

We inspected your seafood processing facility, located at the above address, on August 9, 2001. We conducted this inspection to determine your compliance with FDA's seafood processing regulations Title 21, Code of Federal Regulations, Part 123 (21 CFR 123) and the Good Manufacturing Practice requirements for foods (21 CFR 110).

We found that your firm has a serious HACCP deviation. This deviation causes your refrigerated, ready-to-eat **Caviar** to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act) in that the fish have been prepared, packed or held under insanitary conditions whereby they may be rendered injurious to health. Your serious HACCP deviation is as follows:

> You must have a HACCP plan that lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR Part 123.6(c)(1). However, your firm's HACCP plan for caviar does not list the food safety hazards associated with pathogen growth and toxin formation at the various critical control points listed in your plan. Specifically, caviar packed in reduced oxygen containers is at risk for *Clostridium botulinum* growth and toxin formation. We recommend that you refer to Chapter 13 of the Fish and Fisheries Products Hazards and Controls Guide information relating to control strategies for *Clostridium botulinum*. We also recommend you refer to Chapter 12 for information on possible food safety hazards resulting from pathogen growth other than *Clostridium botulinum*.

The above deviation was pointed out to you during our presentation of the FDA 483 Inspectional Observations, at the close of the inspection. You told our investigator that you would make the corrections. If you have not made the corrections, we expect that you will quickly correct the violation addressed in this letter. We may initiate regulatory action without further notice if you do not correct the violation. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within fifteen working days from receipt of this letter. Your response should outline the specific things you are doing to correct the deviation. You may wish to include in your response documentation such as your revised HACCP plan and copies of completed monitoring records, or other useful information that would assist us in evaluating your correction.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulations and the Good Manufacturing Practice regulations. You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Erlinda N. Figueroa, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, California 94502-7070. If you have questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,

Dennis K. Linsley
District Director
San Francisco District